

Things to consider as we assess next steps for a next generation sling:

- The only difference between TOT and TVT-O is the direction of insertion
 - TOT leads the obturator sling market
 - Both are good products if the surgeon understands how to use the device
 - TOT users feel TVT-O is a blind passage and are more comfortable with the outside-in / top-down approach
- Mini slings have the potential to own a large portion of the market once surgeons understand how to set the tension. This scenario is not very different from that which existed when obturator slings were introduced; it took 3-5 years for techniques to mature
- TVT SECUR should have been launched as two separate products, "U" being 8cm long and "H" being 10 cm long and each having their own IFU. Although 8 cm will work as we have seen, this would have reduced the misuse, confusion and reduced the learning curve.
- Tension of mini-slings is significantly different than what surgeons were used to.
- Although we told surgeons how TVT SECUR needed to be set, they just were not ready to believe us, the sales force was not confident due to early failures, we did not have data to support the thinking, we (Ethicon) never before told surgeons how to set the mesh tension, because there is no one setting!
- Surgeons who did listen to our mesh placement suggestions are today successful with TVT SECUR
- TVT SECUR will NEVER get tighter once placed unlike most other slings to date, because of the short 4 cm of free mesh and laser cut design!
- Most surgeons are not familiar with the anatomy
- Most surgeons have NO idea as to the dynamics of the sling, nor that TVT (Tension-free Vaginal Tape) is actually not tension free, and it never was!
- Most surgeons who use TVT products do not know if it what they use contains mechanically cut or laser cut mesh! Additionally, they don't know we have Laser cut TVT and TVT-O products on the market! ~90/10 MC vs LC sales
- Most surgeons continue to do what they were taught years ago on whatever product they started on and will struggle during change, increased learning curve.
- Only the select few who understand the dynamics of product differences and how those differences impact outcomes.
- Even those who get good results sometimes don't fully understand why, and can't technically explain what they do. They just know what it takes to make it work.
- "Mini-slings" do not have a defined length, TVT SECUR defined it as 8 cm of mesh, and others quickly followed. Scion was going to redefining the mini-sling to achieve consistent placement and efficacy.

- Mini-sling are less painful, therefore patients are more apt to return to normal routines quicker and could dislodge the mesh prior to the ~21 days needed for good tissue in-growth.
- Traditional slings are more painful and patients tend to treat this as a surgical procedure rather than a trip to the doctors office.
- Mini-slings can and will be used in outpatient settings, offices, and surgi-centers and therefore device manufactures should not assume overnight hospital stays and strict 6 week recovering instructions will be adhered to, just because that was the rule of the traditional sling!
- For a mini-sling to be effective in the hands of “many” it should have a positive stretch in an upward direction, which will continue to support the urethra after placement, as did TVT and TVT-O. It must have sufficient holding ability with a high initial slip value, and be easily/reliably placed in multiple tissue structures.

Discussion regarding possible option using Mini-me:

- Professor DeLevals Mini-me 12 cm laser cut concept will face similar challenges to TVT SECUR if produced as he has shown us, for the following reasons.
 - The short laser cut mesh does not stretch the same as a full length mechanically cut TVT-O, or even as much as a full length LC TVT-O meshes.
 - TVT-O MC (mechanically cut) is used, by more than 90% of all TVT-O users!
 - This means that as TVT-O uses are converted they will have early failures as did TVT SECUR until they figure out that a mini-sling needs to be placed differently (tighter) due to the mesh properties
 - The babcock was instituted for TVT-O as an after thought by JDL, to keep the mechanically cut mesh from stretching, roping, and causing retention. It will not be needed if LC mesh is used for mini-me
 - Deleval uses the technique but then nullifies the step by pulling up on the sutures to tension the tape by using a cough test or graday maneuver
 - Surgeons can't agree if these maneuvers are valid, or whether they define a correct setting vs retention
 - The babcock technique will assist in centering the mesh, however during a cadaver lab with JDL he did not achieve mesh symmetry with mini-me and he was using the babcock technique
 - Based on cadaver work and my belief, the mesh should be longer than 12 cm and closer to (~14 cm) when stretched. Additionally, it should have some sort of fixation end to reduce the possibility of movement prior to tissue in-growth
 - This is an important factor which could invalidate JDL's clinical data, due to the strict recovery protocol and mandatory over night hospital stay protocol
- What is needed to make mini-me as shown by JDL successful
 - A clinical should be conducted first with multiple surgeons and patient release opinions/restrictions ranging from overnight and 6 weeks of strict recovery to in-

out in one hour and limited to no restrictions, as some believe. It also needs to assess how mesh tension will be or was established across the surgeons.

- Use mechanically cut mesh at ~12 which should stretch to ~14 cm
- Create an end on the mesh by either folding and U/S welding or adding a small patch of Ethisorb and then U/S welding
- Challenges that will be faced regarding mini-me as shown by JDL
 - It is not a single incision sling
 - Mini-sling users of mini arc, TVT SECUR, and Adjust will not see Mini-me as an advantage
 - Has greater surgical risks than a mini-sling that does not pass through the obturator space
 - Reduction in leg pain is not considered a real issue
 - Most conversions will be from cannibalization of TVT-O, depending on the ASP the dollar increase may not be significant
 - You will not be able to say it is the same as TVT-O, but only shorter
 - ▪ Tension setting of the mesh is different
 - ▪ The periurethral incisions are not as deep and not as wide
 - ▪ The internus muscle and obturator membrane are not punctured
 - If produced as JDL has suggested, it does not have the efficacy that he achieved and the variability will cause concerns.
 - If Mini-me is altered as I have suggested will his data be considered valid and will need to be redone?
- Positives regarding mini-me
 - JDL and his name
 - His dedication to teach and train other surgeons

Discussion regarding possible Option#3 using Next Generation TVT SECUR:

- The 10 cm laser cut concept with face similar challenges to TVT SECUR if surgeons do not understand how it MUST be tensioned.
 - The longer laser cut mesh will stretch slightly more than the current 8 cm TVT SECUR! 6 cm vs 4 cm of exposed free mesh
 - Easier to hit multiple tissue structures
 - TVT SECUR users should see this as an advantage
 - Users will not be able to go back and forth between "U" and "H", Option #3 will be for "H" only
 - The Ethisorb is superior for early fixation to tissue
 - No clinical would be needed!
- What is needed to make Option#3 successful
 - Use clinical data from TVT SECUR "H" and motivate the sales force
 - Ensure that sales reps understand how the mesh must be tensioned
 - Good surgeons and rep training
 - Clearly differentiate Option #3 from TVT SECUR "U &H"
- Challenges that will be faced regarding Option #3

- The device will still have a cutting edge and competitors will site increased bleeding verses anon-cutting tip even if bleeding is reduce due to the pathway being closer to the ischial pubic ramus.
- Many conversions will be from cannibalization of TTV SECUR "H"
- Positives regarding Option #3
 - Build off of TTV SECUR and current data
 - Easier to teach
 - Can better sell against other competitive mini-slings that only fixate in the internus muscle
 - Still no or little pain

Discussion regarding possible Next Generation Scion:

- The 12 cm Shaped laser cut which will stretch like mechanically cut mesh to ~14 cm
 - The concept will reduce the challenges faced by TTV SECUR and surgeons who do not understand how a mini-sling should be tensioned.
 - Should behave like what our TTV user are used to and get equal efficacy to TTV-O
 - Uses the brand equity and human factors of TTV-O
 - Device will have around body and no cutting edges
 - Easily hits 3 tissue structures, 2 structures more than TTV SECUR and Mini-arc, and 1 structure more than Mini-Me and Bards Adjust
 - TTV-O, TOT and mini-sling users should see this as an advantage
 - Safer than TTV-O as it does not travel as far
 - Should be seen as a next generation of TTV-O rather than a mini-sling
 - Will have superior initial slip fixation to TTV SECUR and Mini-arc
- What is needed to make Scion successful
 - Use clinical data from study and motivate the sales force
 - Ensure that sales reps understand how the mesh must be positioned
 - Good surgeon and rep training
- Challenges that will be faced regarding Scion
 - The device will need clinical data and not be launched until Q1 2001
 - Many conversions will be from cannibalization of TTV SECUR "H", and TTV-O
- Positives regarding Scion
 - Scion will be a superior product and will command the market
 - Build off of TTV-O brand equity
 - Easier to teach
 - Has an absorbable tip, not pointy and hard PP left
 - Can better sell against TOT and other competitive mini-slings
 - Still no or little pain

Dan Smith - November 13, 2008